10. A method for preventing the development of, or for treating enlarged, non-cancerous prostate glands in mammals comprising the steps of administering a therapeutic dosage of eugenol.

REMARKS

This is a response to the Office Action dated 10/09/02.

Claim 5 is objected to under 37 CFR 1.75(c), claims 1-3 are rejected under 35 USC 112 2nd paragraph, claims 1, 3, 6 and 8 are rejected under 35 USC 102, and all claims stand rejected under 35 USC 103 in view of the cited prior art.

Claims 1 through 7 have been canceled, and a new claim 10 has been added, all such surviving claims being believed to be patentably distinct over the cited prior art.

Applicant will first address Claim 8.

Applicant acknowledges that the cited reference teaches a therapeutic agent of 2ME to inhibit tumor promotion. However, there is no suggestion in the art for administering 2ME in order to prevent or treat mere enlargement of the prostate, a condition which, at its closest juxtaposition to the cited art, precedes any need for treatment in the cancer realm and which may not relate or lead to cancer at all. While the focus of the reference is the administration of 2ME to tumors (cancerous or precancerous), applicants invention is directed towards the treatment of an enlargement of the prostate gland itself.

Because enlarged prostate is a ubiquitous problem (greater even than prostate cancer - itself -- a leading killer of men), were there any suggestion in the prior art to the level of rendering it obviousness to try using 2ME to treat or prevent enlarged, non-cancerous prostate as such, it would clearly be discussed in the literature. Such appears to the undersigned to be

absent from the literature or known prior patents. This, therefore, appears to be a clear case of long-felt, but unsatisfied need for which no suggestion of the claimed solution appears in the art.

Concerning the use of 2ME and eugenol in combination, applicant further acknowledges that the cited references teach the administration of eugenol to treat cancerous or precancerous cell populations and hyperplasia.

Examiner's suggestion that it is obvious to combine two or more suspected anti-cancer agents to achieve an enhanced effect, over that achieved by each individual agent alone, certainly warrants comment. In this instance, however, combining eugenol with 2ME would not appear at all obvious to ones familiar with the work on eugenol for a number of independent reasons.

Firstly, the suspected efficiency of eugenol was only known in relation to certain types of cancers (e.g., skin). Secondly, the suggestions in the literature that eugenol might be effective in treating prostate cancer are merely extrapolations of indirect indications of such a possible effect, without any supporting evidence or direct data of work on prostate cell lines. Thirdly, recent investigations by the present inventors indicate that eugenol alone is not effective in arresting growth of prostate cancer cells (declaration support will be provided upon request), but shows promise in treating or preventing enlarged prostate conditions. Finally, eugenol is known to be, not only ineffective against certain cancer cells, but to be an actual aggravating factor against some (breast cancer, for example). Any mere assumption of eugenol's efficacy (or even safety) against any one form of cancer, merely because of suspected efficacy against others, is known in the art to be a dangerous assumption, and not one to be made without direct investigation. No known prior art provides any enabling information to allow one to actually apply eugenol in combating or preventing prostate cancer, much less non-cancerous, enlarged prostate.

Anyone actually, directly researching the efficacy of eugenol against prostate cancer would find that eugenol is not something that appears useful in treating prostate cancer, much less non-cancerous enlarged prostate. It is, therefore, further removed from the realm of the obvious that one would combine eugenol with another anti-cancer agent to achieve an enhanced effect of the latter agent in the prostate cancer realm. It is farther still removed from the obvious that such combination would be efficacious in the enlarged, non-cancerous prostate gland realm. The synergistic effect of 2ME and eugenol in combination is not suggested anywhere in the prior art, and, factors as describe above, in fact, suggest that, at the time of the present invention, one skilled in the art would assume that such a combination would be (at best) harmless, but useless, and (at worst) harmful to recipients.

This should, therefore, certainly neutralize the effect of references such as Liao as a basis for an obviousness rejection (Liao merely suggests, because of an apparent effect of eugenol on 5-alphay reductase, that eugenol may be effective against prostate cancer).

With respect to newly added Claim 10, the present inventors' work in gaining an understanding of the apparent mechanism for preventing or treating an enlarged prostate as opposed to cancerous or precancerous cell populations is pioneering work. Using the present agents at such time and in such manner as to achieve the effect claimed in Claim 10 is nowhere taught or suggested in the prior art.

In view of the above, it is submitted that Claims 8 - 10 are in condition for allowance. Reconsideration and withdrawal of the rejections and objections are hereby requested.

If impediments to allowance of Claims 8 - 10 remain and a telephone conference or in-person interview between the undersigned (and inventors) and Examiner would help remove

such impediments in the opinion of the Examiner, such is respectfully requested.

Respectfully submitted,

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